

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Clinical Pharmacology Subcommittee of the Advisory Committee for
Pharmaceutical Science; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB
27
Display Date 9.27.02
Publication Date 9.30.02
Certifier G. E. Kelly

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 23, 2002, from 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

oc02240

3898

NMI

Agenda: The subcommittee will discuss: (1) Consideration of investigational pharmacokinetic studies to identify patient populations at risk, (2) methods used to adjust dosing given the availability of exposure-response information, (3) use of exposure-response relationships in the Pediatric Study Decision Tree, (4) questions to be asked of the pediatric database, and (5) scientific and practical considerations in the use of pharmacogenetic tests to determine drug dosage and administration.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 14, 2002. Oral presentations from the public will be scheduled between approximately 12 noon and 1 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 14, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

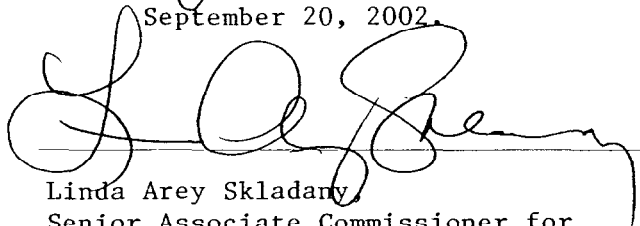
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electric outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kathleen Reedy at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: Sept 20 2002

September 20, 2002.



Linda Arey Skladany,
Senior Associate Commissioner for
External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

